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ATTORNEY FOR PLAINTIFF
UNITED STATES OF AMERICA

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BUTTE DIVISION

UNITED STATES OF AMERICA, Plaintiff, vs. KRISTJAN THORKELSON, Defendant.	14-CR-27-BU-DLC OFFER OF PROOF
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Plaintiff, United States of America, by and through counsel of record, Paul Joseph, Special Assistant United States Attorney for the District of Montana, hereby files its Offer of Proof.

THE CHARGE

The defendant, Kristjan Thorkelson, has been charged by Superseding Information filed on December 12, 2017, with misprision of felony, in violation of 18 U.S.C. § 4.

PLEA AGREEMENT

There is a plea agreement in this case; the defendant will plead guilty and waive formal presentment of an Indictment to a Grand Jury.

The United States presented any and all formal plea offers to the defendant in writing. The plea agreement entered into by the parties and filed with the court represents, in the government's view, the only and most favorable offer extended to the defendant. *See Missouri v. Frye*, 132 S.Ct. 1399 (2012).

Pursuant to the plea agreement, governed by Rule 11(c)(1)(C), *Federal Rules of Criminal Procedure*, the defendant will plead guilty to the single count in the Superseding Information.

PENALTIES

This offense carries a maximum punishment of three years imprisonment, a term of probation of five years, a \$250,000 fine, and a \$100 special assessment.

ELEMENTS

In order for the defendant to be found guilty of the charge of misprision of a felony, in violation of 18 U.S.C. § 4, the United States must prove each of the following elements beyond a reasonable doubt:

First, the principal committed and completed the felony alleged;

Second, that the defendant had knowledge of the crime committed by the principal;

Third, the defendant failed to notify authorities; and

Fourth, the defendant took steps to conceal the crime.

ANTICIPATED EVIDENCE

If this case were tried in United States District Court, the United States would prove the following:

A. Underlying Felony

In April 2010, the Food and Drug Administration (FDA), Office of Criminal Investigations (OCI) began to investigate Canada Drugs Ltd. and related entities ("Canada Drugs") for importing and distributing misbranded and unapproved prescription drugs, including cancer medication, to consumers throughout the United States. The criminal investigation established that the drugs distributed in the United States by Canada Drugs were not approved by the FDA as required by

law, and were misbranded as defined in the Food Drug and Cosmetic Act (FDCA), pursuant to 21 U.S.C. §§ 352(c), 352(o), and 352(f), as the products contained language on the labeling that was not in English, failed to contain adequate warnings and required statements, and lacked adequate directions for use. Since 2001, the defendant has been, and remains, the CEO of Canada Drugs.

In 2009, Canada Drugs acquired other companies engaged in similar illegal prescription drug importation and distribution activities and used the brand names, drug inventories, and customer lists of those companies to further its illegal operation. The defendant was personally involved in the acquisition of other companies, including Montana Healthcare Solutions, also known as MHCS. A majority of the prescription drugs, including cancer medication that needed to be stored at consistently cold temperatures, was intended solely for foreign markets.

Canada Drugs created a new entity, Rockley Ventures, Ltd. (“Rockley Ventures”), to operate its new clinical line of products. Rockley Ventures was created with capital from Canada Drugs and was operated out of Barbados. River East Supplies, Ltd. (“River East Supplies”), a subsidiary of Canada Drugs, was the primary supplier of the clinical arm of Canada Drugs with products for shipment to the United States.

In 2009 and 2010, Thorkelson and other Canada Drugs executives negotiated for the purchase of Montana Healthcare Solutions from Montana resident Paul Bottomley. The transaction was finalized in October 2010 when Bottomley sold Montana Healthcare Solutions to Canada Drugs and Rockley Ventures for \$5 million. After the purchase, Canada Drugs continued to use Montana Healthcare Solutions' bank account at First Montana Bank to deposit funds from physicians for sales of unapproved and misbranded prescription drugs purchased in the United States. The funds from that account at First Montana Bank were then transferred to accounts of Canada Drugs entities in Canada and Barbados.

During the criminal investigation, it was discovered that entities affiliated with Canada Drugs had distributed in the United States counterfeit cancer drug Avastin (American version) and counterfeit cancer drug Altuzan (Turkish version). The counterfeit Altuzan was distributed in 2011 by River East Supplies, the subsidiary which conducted Canada Drugs' operations in the United Kingdom. Substance analysis conducted by the FDA revealed that the Altuzan vials were counterfeit as they contained no active ingredient.

The counterfeit Avastin distributed by Canada Drugs-affiliated entities was discovered in December 2011, when the United Kingdom Medicines and

Healthcare Products Regulatory Agency notified the FDA of a potential counterfeit batch of the oncology drug which River East Supplies had purchased from a supplier in the European Union. Specifically, River East Supplies had acquired 167 packages of Avastin and had transferred 41 of those packages to a drop shipper used by Canada Drugs in the United States. That drop shipper confirmed that they had already distributed 36 of the 41 vials of Avastin to physicians in the United States. Subsequent lab tests confirmed that the Avastin was counterfeit and contained none of the active ingredient bevacizumab that is found in legitimate versions of the oncology drug.

By at least early 2012, Thorkelson and other employees and executives of Canada Drugs were aware that the Canada Drugs affiliated companies had sold packages of suspect Avastin and Altuzan to medical clinics in the United States. Yet, at that time, Thorkelson failed to notify any authorities regarding the suspect product. Further, Thorkelson and his co-conspirators took steps to conceal the same. For example, in March 2012, Thorkelson sent an email message to all Canada Drugs employees falsely stating that Canada Drugs had “absolutely no connection to selling or offering Avastin.” Thorkelson further falsely stated in that email message that Canada Drugs sold “only prescription maintenance medications to individuals.” By the time that email message had been sent,

employees and executives of Canada Drugs, including Thorkelson, were aware that the statements in that message were false, and that Canada Drugs and related entities had already taken efforts to recall the suspect Avastin from customers in the United States.

As stated herein, Canada Drugs and its executives and subsidiaries committed the felony crime of introducing, and delivering for introduction, into interstate commerce misbranded drugs with the intent to defraud and mislead, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). The defendant had knowledge of the commission of this felony crime. The defendant failed to notify authorities of the commission of the crime, and took steps to conceal the crime.

DATED this 9th day of April, 2018.

KURT G. ALME
United States Attorney

/s/ Paul Joseph
Special Assistant United States Attorney
Attorney for Plaintiff

CERTIFICATE OF COMPLIANCE

Pursuant to D. Mont. LR 7.1(d)(2) and CR 12.1(e), the attached United States' Offer of Proof is proportionately spaced, has a typeface of 14 points or more, and has a body containing 1,223 words.

/s/ Paul Joseph

Special Assistant United States Attorney
Attorney for Plaintiff